

### **REMARKS**

Applicants' agents wish to thank Examiner Prone for the opportunity to discuss this matter on September 18, 2007.

Claim 1 has been amended herein as suggested by the Examiner to correct an obvious typographical error.

#### **Concerning 35 USC § 112, first paragraph**

The examiner maintained the rejection claims 1-15, 17-24 and 45-50 under 35 USC §112, first paragraph, for assertedly lacking written descriptive support in the specification. Specifically, the examiner was of the opinion that the previous amendment to claim 1 to recite that the claimed implant is dehydrated "in its entirety" is not supported and that the specification only describes dehydrating filament and matrix portions of the implant. As discussed with the examiner, the applicants disagree.

Previously, the applicants pointed out that in the specification as originally filed, claim 27 recites dehydration of an implant prepared by the method of claim 25. The two claims are reproduced below.

25. A method of preparing an implant for connective tissue substitution in an animal, said method comprising the steps of: a) providing a set of bone anchors by joining a pair of bone plugs at their proximal ends by at least one support filament; and b) incubating at least one time said set of bone anchors of step a) in a solution containing matrix forming molecules for a period time sufficient for the formation of at least one matrix layer around said support filament, wherein said matrix layer has a thickness sufficient to allow for colonization by cells, and wherein said incubation is performed under conditions in which are induced waves, vibrations, cyclic tractions, and/or static tractions of said implant.

27. The method according to claim 25, wherein said implant is dehydrated, lyophilized and/or chemically treated prior to implantation.

Claim 25 thus describes an implant as comprising bone anchors formed with bone plugs joined by a support filament, the entirety of which is incubated in a solution of matrix-forming molecules that forms a matrix layer around the support filament. With the entire implant thus formed, claim 27 requires the implant to be dehydrated, lyophilized and/or

chemically treated prior to implantation. This step necessarily requires some type of treatment on the whole implant (i.e., the implant in its entirety), and not on individual components of the implant. The process step recited in original claim 27 is consistent with disclosure in the specification.

For example, paragraphs 96 through 100 in the specification as originally filed describe production of bioengineered ligament substitutes (i.e., implants). In paragraphs 96 and 97, bone anchors are provided wherein holes are made in each and the anchors are connected with surgical thread. Paragraphs 98 and 99 describes alternative collagen solutions in which the thus formed implant is then incubated. Paragraph 100 then describes incubation of the two bone anchors linked by the surgical thread (i.e., the implant) in the collagen solution such that collagen scaffolds are cast between the two anchors. At this point, preparation of the implant in its entirety as recited in original claim 25 is complete, and paragraph 100 then states that this tissue construct (i.e., the entire implant) is put into a desiccator and is completely dehydrated within about two to three hours.

Similarly, paragraphs 105 through 109 in the specification as originally filed describes preparation of periodontal ligament substitutes (i.e., implants) wherein teeth pieces are provided, hole are drilled in each, and the pieces are then connected with surgical thread as specifically described in paragraphs 105 and 106. As above, alternative collagen solutions are described in paragraphs 107 and 108, and the incubation process is described in paragraph 109 wherein a collagen scaffold is cast between the tooth anchors joined by the surgical thread. After this incubation step, the complete tissue construct (i.e., the implant in its entirety) is desiccated. While paragraph 109 goes on to describe how another layer of collagen can be added after desiccation, this extra step is simply an alternative embodiment that need not be carried out.

In each of these disclosures, the implant in its entirety is defined as having two anchors connected by a filament and including a collagen casting. It is explicitly disclosed that this entire implant is dehydrated, and not simply individual components. Accordingly, the applicants submit that the specification fully supports the subject matter of claim 1 as previously amended and the rejection for assertedly lack of written description must be withdrawn.

### **The rejection under 35 USC §103**

In view of the asserted basis for the rejection described above under section 112, first paragraph, claims 1 through 15, 17 through 24 and 45 through 50 were rejected under 35 USC §103 as being directed to subject matter allegedly rendered obvious by the disclosure of Altman in view of the disclosure of Caplan.

Inasmuch as neither reference teaches that an entire implant is dehydrated prior to implantation, the combination does not disclose all limitation of the claims and therefore cannot support an assertion of obviousness. Accordingly, the rejection must be withdrawn.

### **CONCLUSION**

In view of the remarks herein, the applicants believe that all claims are now in condition for allowance and respectfully request notification of the same.

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Respectfully submitted,

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